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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,463	11/23/2005	Ying Zhang	200507001-1	3795

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EXAMINER	
HENRY, MICHAEL C	
ART UNIT	**PAPER NUMBER**
1623	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	01/30/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

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Office Action Summary	Application No.	Applicant(s)	
	10/538,463	ZHANG ET AL.	
	Examiner	Art Unit	
	Michael C. Henry	1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-10* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-10* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *06/10/05*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-10 are pending in application

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement filed complies with the provisions of 37 CFR 1.97, 1.98 and MPEP § 609. It has been placed in the application file and the information referred to therein has been considered as to the merits.

Claim Objections

Claim 3 is objected to because of the following informalities: The claim recites the phrase "triterpenids" which appears to be a typographical error. It appears that the term "triterpenids" should be replaced with the word "triterpenoids". Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 2, 8-10 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The phrase "pentacyclic triterpenoids of friedelin, " in claim 2, renders the claims indefinite. More specifically, it is unclear how said compounds must be related to friedelin to be considered "pentacyclic triterpenoids of friedelin".

Claims 8-10 provides for "the use of the composition or the use of total triterpenoid sapogenins ....." but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 8-10 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd.* v. *Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966). Dependent claims 15-19 which also recite the use of, are also encompassed by this rejection.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Ohmoto et al. (Shoyakugaku Zasshi (1974), 28(1), pages 1-6).

In claim 1, applicant claims a composition of total triterpenoid sapogenins extracted from bamboo, wherein the content of total tritepenoid sapogenins in the composition is 10-90% as determined by vanillic aldehyde and perchloric acid colorimetry using friedelin as a standard, and the contents of friedelin and lupenone are 5-35% and 1-10% as determined by GC-MS, respectively. Claim 2 is drawn to the composition of claim 1, wherein the content of total triterpenoid sapogenins is 40-80%, and the content of friedelin and lupenone are 15-25% and 3-6%, respectively. Claim 3 is drawn to the composition of claim 1 wherein the total triterpenoid sapogenins comprise pentacyclic triterpenids of friedelin, lupenone and their homologous compounds and wherein the triterpenod sapogenins have physical properties and gives specific IR and UV spectrograms.

Ohmoto et al. disclose a composition comprising triterpenoid sapogenins and related compounds that are extracted from bamboo (Arundinarieae) of Gramineae plants wherein said composition comprises friedelin, lupenone and other pentacyclic triterpenoids (see abstract). It should be noted that Arundinaria is a genus of bamboo commonly known as canes. Ohmoto et

al. do not explicitly disclose the total % of triterpenoid sapogenins and the % of friedelin and lupenone in their composition. But, the silence of Ohmoto et al. does not mean that their composition does not contain the same said total % of triterpenoid sapogenins and % of friedelin and lupenone. Furthermore, it should be noted that Ohmoto et al.'s composition is obtained from the same source as applicant's composition and comprises the same components or substances (friedelin and lupenone) as applicant's composition and consequently may well have the same total percentages (%) of triterpenoid sapogenins and the same % of friedelin and lupenone. Ohmoto et al. anticipates the claims if their composition has the same total percentages (%) of triterpenoid sapogenins and the same % of friedelin and lupenone. Ohmoto et al. renders the claims as being obvious if the total percentages (%) of triterpenoid sapogenins and the % of friedelin and lupenone in their composition is substantially close to the total percentages (%) of triterpenoid sapogenins and the % of friedelin and lupenone in applicant's composition. Claims 2 and 3 are also encompassed by this rejection since Ohmoto et al. composition also comprises other pentacyclic triterpenoids and since Ohmoto et al silent about the physical properties and the IR and UV spectrograms of their composition does not mean that their composition does not have the same physical properties and the same IR and UV spectrograms as applicant's composition.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 4-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Staack Reis Machado et al. (EP 1122259 A2).

In claim 4, applicant claims a method for extracting total triterpenoid sapogenenins from bamboo comprising the steps of: (a) mixing the material with the supercritical CO_2 fluid, thereby making the low-polar substances of bamboo such as free triterpenoids dissolve in CO_2 fluid, wherein the material is selected from the group consisting of poles, branches, leaves, shoots, shoot, sheaths and roots of bamboo in Gramineae family or their mixture, and the extraction temperature is 50-65 °C and the pressure is 25-35 Mpa; (b) changing the pressure of CO_2 fluid containing free tritepenoids to gasify CO_2, and separating the total triterpenoid sapogenins, wherein the separation temperature is 35-45 °C and the pressure is 5-10 Mpa. Claims 5-7 are drawn to the method of claim 4 wherein the bamboo material is in specific powdered form, specific amounts of CO_2 is used and recycled, the bamboo powder specifically extracted for given time, specific entrainer including ethanol is used and specific kinds of bamboo are used.

Staack Reis Machado et al. disclose a method method for extracting triterpenoids (including friedelin and related compounds) from the ceroid fraction of cork smoker wash solids comprising mixing the material with the supercritical CO_2 fluid, thereby making the low-polar substances of said material such as free triterpenoids dissolve in CO_2 fluid, wherein and the extraction temperature is between 30-50 °C and the pressure is between 4-40 Mpa (see abstract, example 1, claims). Staack Reis Machado et al. disclose that the pressure and temperature may be changed during the exraction, or may be constant, and carries out the separation at separation temperature between 20-120 °C and pressure between 40 Mpa and atmospheric pressure (see

abstract, example 1, claims). Furthermore, Staack Reis Machado et al. disclose that the co-solvent can be ethanol (see claim 5).

The difference between applicant's claimed method and the method of Staack Reis Machado et al. is that Staack Reis Machado et al. do not extract their triterpenoids from the same plant (bamboo), as applicant. However, Staack Reis Machado et al. disclose that compounds including triterpenoids can be extracted from natural origins and that supercritical fluids can be applied in the extraction of natural products (see page 2, section [0009]-[0011]). This implies that triterpenoids can be extracted or isolated from natural origins such as from plants (e.g. (bamboo plant).

It would have been obvious to one having ordinary skill in the art, at the time the claimed invention was made, to have used the method of Staack Reis Machado et al. to extract triterpenoids from any plant such as bamboo in order to use them to treat conditions such as rheumatoid diseases, based on factors such as availability, cost, convenience and/or need.

One having ordinary skill in the art would have been motivated to use the method of Staack Reis Machado et al. to extract triterpenoids from any plant such as bamboo in order to use them to treat conditions such as rheumatoid diseases, based on factors such as availability, cost, convenience and/or need. It should be noted that a skilled artisan would be motivated to modify the physical parameters such as temperature, concentration, time and repetition or types of extractions in order to optimize the process conditions and physical variables such as amounts, % yield and/or purity of product (i.e., phytosterols). It should be noted that merely modifying the process conditions such as temperature and concentration is not a patentable modification absent a showing of criticality. In re Aller, 220 F.2d 454, 105 U.S.P.Q. 233 (C.C.P.A. 1955).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael C. Henry whose telephone number is 571-272-0652. The examiner can normally be reached on 8.30am-5pm; Mon-Fri. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Shaojia A. Jiang can be reached on 571-272-0627. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1623

January 19,2007.